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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,904	04/06/2006	Masazumi Yasumoto	1422-0714PUS1	7136

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EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
07/19/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)
	10/574,904	YASUMOTO ET AL.
	Examiner	Art Unit
	SEAN MCGARRY	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/06/2006;7/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence alignment*.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of "juxtamembrane region"/SEQ ID NO:27, SEQ ID NO:8 and 9, U6 promoter and retrovirus vector in the reply filed on 5/02/2011 is acknowledged.

The examiner notes that SEQ ID NOS:7 and 38-40 are examined herein. SEQ ID NOS 8 and 9 are 21mers targeted to SEQ ID NO:7 and SEQ ID NOS: 39 and 40 are 19mers targeted to SEQ ID NO:38. Each of SEQ ID NOS:38-40 are embraced within SEQ ID NOS:7-9 respectively.

Priority

Applicant cannot rely upon the foreign priority papers to overcome any rejection in this Official Action because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Khvorova et al [US20070031844].

Khvorova et al disclose SEQ ID NOS: 177,846; 177,941; 182,471; 182,476; 182,482; 182,490; and 182,505 which are all siRNA compounds that target within the instant juxtamembrane region defined by SEQ ID NO:27. Kvorova et al disclose that the siRNA compounds of their invention can be included in kits. The siRNA compounds disclosed by Kvorova are targeted to FLT3 which has been disclosed by Khvorova to be a target for cancer therapy. See paragraphs 12,67, 388 and 403, for example. It is noted that SEQ ID NO:182,476 of Kvorova et al corresponds to a siRNA that corresponds to the recited SEQ ID NO:8and 9 siRNA and the SEQ ID NO:39 and 40 siRNA. Applicant should note that the language utilized in the instant claims only requires that the siRNA comprise “a” sequence from SEQ ID NO:8 or 9 or 39 or 40, for example. The siRNA of SEQ ID NO:182,476 clearly targets and corresponds to the target defined by SEQ ID NO:7 and 38 of the instant invention. An alignment of the sequences of Khvorova et al and the instant SEQ ID NO:27 is attached to this Official Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khvorova et al [US20070031844] in view of Shen et al. [FEBS Letters Vol. 539:111-114, 2003].

Khvorova et al disclose SEQ ID NOS: 177,846; 177,941; 182,471; 182,476; 182,482; 182,490; and 182,505 which are all siRNA compounds that target within the instant juxtamembrane region defined by SEQ ID NO:27. Khvorova et al disclose that the siRNA compounds of their invention can be included in kits. The siRNA compounds disclosed by Khvorova are targeted to FLT3 which has been disclosed by Khvorova to be a target for cancer therapy. See paragraphs 12,67, 388 and 403, for example. It is noted that SEQ ID NO:182,476 of Khvorova et al corresponds to a siRNA that corresponds to the recited SEQ ID NO:8and 9 siRNA and the SEQ ID NO:39 and 40

siRNA. Applicant should note that the language utilized in the instant claims only requires that the siRNA comprise “a” sequence from SEQ ID NO:8 or 9 or 39 or 40, for example. The siRNA of SEQ ID NO:182,476 clearly targets and corresponds to the target defined by SEQ ID NO:7 and 38 of the instant invention. Khvorova et al have suggested the use of vectors to express siRNAs of their invention (see paragraph 277, for example]. Khvorova et al have also taught that the siRNAs of their invention can be from 18-30 nucleotide in length which renders the instantly recited siRNAs based on SEQ ID NOS:8, 9, 39, and 40 obvious (see paragraph 105, for example). Khvorova et al do not specifically demonstrate the use of retroviral vectors or teach the recited promoter of the instant invention.

Shen et al have taught the use of viral vectors for the purpose of cancer therapy. Shen et al assert that their vector represents an expansion of RNAi strategy to human cancer therapy. Shen et al further have taught that it was known in the art the use of retroviral vectors utilizing U6 promoters for siRNA expression (see Introduction on page 111, for example). It has been taught that vectors allow for efficient delivery of siRNA to mammalian cells.

The use of siRNA compounds for treating diseases such as cancer was known in the art at the time of invention. The prior art furthermore has specifically taught to target Flt-3 in the treatment of cancer and even further has taught the use of siRNA for the purpose of treating cancer. The prior art has also taught the use of viral vectors such as retroviral vectors utilizing U6 promoters for the treatment of cancer. The instant

invention amounts to a combination of elements known in the art where the elements of the prior art have been taught to be utilized as in the instant invention.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khvorova et al in view of Shen et al. [FEBS Letters Vol. 539:111-114, 2003], and Levis et al [BLOOD Vol. 99(11):6/1/2002].

Khvorova et al [US20070031844] disclose SEQ ID NOS: 177,846; 177,941; 182,471; 182,476; 182,482; 182,490; and 182,505 which are all siRNA compounds that target within the instant juxtamembrane region defined by SEQ ID NO:27. Khvorova et al disclose that the siRNA compounds of their invention can be included in kits. The siRNA compounds disclosed by Khvorova are targeted to FLT3 which has been disclosed by Khvorova to be a target for cancer therapy. See paragraphs 12,67, 388 and 403, for example. It is noted that SEQ ID NO:182,476 of Khvorova et al corresponds to a siRNA that corresponds to the recited SEQ ID NO:8and 9 siRNA and the SEQ ID NO:39 and 40 siRNA. Applicant should note that the language utilized in the instant claims only requires that the siRNA comprise “a” sequence from SEQ ID NO:8 or 9 or 39 or 40, for example. The siRNA of SEQ ID NO:182,476 clearly targets and corresponds to the target defined by SEQ ID NO:7 and 38 of the instant invention. . Khvorova et al have suggested the use of vectors to express siRNAs of their invention

(see paragraph 277, for example]. Khvorova et al have also taught that the siRNAs of their invention can be from 18-30 nucleotide in length which renders the instantly recited siRNAs based on SEQ ID NOS:8, 9, 39, and 40 obvious (see paragraph 105, for example). Khvorova et al do not specifically demonstrate the use of retroviral vectors or teach the recited promoter of the instant invention or a combination of flt3 inhibitors.

Shen et al have taught the use of viral vectors for the purpose of cancer therapy. Shen et al assert that their vector represents an expansion of RNAi strategy to human cancer therapy. Shen et al further have taught that it was known in the art the use of retroviral vectors utilizing U6 promoters for siRNA expression (see Introduction on page 111, for example). It has been taught that vectors allow for efficient delivery of siRNA to mammalian cells.

Levis et al have taught the use of FLT-3 targeted tyrosine kinase inhibitor that prolonged survival in mouse models of leukemia.

The use of siRNA compounds for treating diseases such as cancer was known in the art at the time of invention. The prior art furthermore has specifically taught to target Flt-3 in the treatment of cancer and even further has taught the use of siRNA for the purpose of treating cancer. The prior art has also taught the use of viral vectors such as retroviral vectors utilizing U6 promoters for the treatment of cancer. The instant invention amounts to a combination of elements known in the art where the elements of the prior art have been taught to be utilized as in the instant invention. It is not inventive to combine elements that are known to have similar effects. For example that art has taught the inhibitor of Levis for treating cancer and has also taught siRNA for the

treatment of cancer. Furthermore, both compounds were taught in the art to inhibit the same target Flt 3 activity. It is well established that the combination of compounds that are recognized by the art to have the same effect is obvious. Applicant has not demonstrated any unexpected effects from the combination of known compounds that are each known to provide for treatment of cancer via inhibition of Flt3.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN MCGARRY whose telephone number is (571)272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on (571) 272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635

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